UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	Criminal No. 09-CR-10330 GAO
v.	Violation:
STRYKER BIOTECH, LLC,	21 U.S.C. §§331(k), 333(a)(1) and 352 (Misbranding)
Defendant.	

SUPERSEDING INFORMATION

The United States Attorney charges that:

General Allegations

At all times material to this Superseding Information, unless otherwise alleged:

The FDA and FDCA

1. The United States Food and Drug Administration ("FDA") was an agency of the United States government entrusted with responsibility for protecting the health and safety of the public by assuring, among other things, that medical devices intended for use in the treatment of humans were safe and effective for their intended uses and that the labeling of such medical devices bore true and accurate information. Pursuant to this statutory mandate, FDA regulated the manufacture, labeling, and shipment in interstate commerce of such devices.

2. Under the Federal Food, Drug and Cosmetic Act (Title 21, United States Code, §301-397, the "FDCA"), the term "device" included an instrument, apparatus, implant, machine . . . or other similar or related article . . . which is . . . intended for use in . . . the treatment or prevention of disease of man . . . or intended to affect the structure or any function of the body of

man . . . which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. §321(h).

3. The FDCA required every manufacturer of a new device to submit proposed written labeling to the FDA for approval. "Labeling" meant all labels and other written, printed or graphic matter "(1) upon any article or any of its containers or wrappers or (2) accompanying such article." 21 U.S.C. § 321(m).

4. Labeling for medical devices was required to contain both (1) adequate directions for use, and (2) adequate warnings, among other warnings, against unsafe methods or application as were necessary for the protection of users. 21 U.S.C. § 352(f).

5. A prescription medical device was "misbranded" if, among other things, its labeling lacked adequate directions for use and it did not qualify for an exemption to this requirement. 21 C.F.R. §§ 801.5, 801.109.

6. Introduction or delivery for introduction into interstate commerce of a misbranded medical device was prohibited by law. 21 U.S.C. § 331(a). In addition, the law prohibited the doing of any other act with respect to a medical device when the device was held for sale after shipment in interstate commerce that resulted in the device being adulterated or misbranded. 21 U.S.C. § 331(k).

The Defendant

7. **STRYKER BIOTECH, LLC** (hereinafter "**STRYKER BIOTECH**") was a limited liability corporation with a principal place of business in Hopkinton, Massachusetts.

STRYKER BIOTECH was a subsidiary of Stryker Corporation, a company whose shares were publicly traded on the New York Stock Exchange.

8. At all relevant times, **STRYKER BIOTECH** was engaged in the manufacture and sale of medical devices for human use, including medical devices for use in healing of fractured or broken bones, including: (a) OP-1 Implant, which was an implant to promote growth in certain long bone non-unions; (b) OP-1 Putty, which was a putty to promote bone growth in certain spinal fusions; and (c) Calstrux, which was a bone void filler for surgically created bone defects or bone defects resulting from traumatic injury. **STRYKER BIOTECH** shipped these devices in interstate commerce from its manufacturing facility in New Hampshire to many states, including Massachusetts, California, Florida, Texas, North Carolina, New York, Ohio, Michigan and others.

COUNT ONE: **21 U.S.C. §§331(k), 333(a)(1) & 352(f) - Distribution of a Misbranded Device**

9. The allegations contained in paragraphs 1 through 8 are realleged and incorporated herein as if set forth in full.

10. On December 11, 2006, in the District of Massachusetts and elsewhere, the defendant,

STRYKER BIOTECH, LLC,

did, while quantities of OP-1 were held for sale after the devices had been shipped in interstate commerce, provide and caused to be provided written instructions for administration and use of a mixture of OP-1 and Calstrux, which instructions were not approved by the FDA as part of the labeling for OP-1, and which acts resulted in OP-1 being misbranded, such instructions being provided by a member of the **STRYKER BIOTECH** sales force to a surgeon.

All in violation of 21 U.S.C. §§331(k), 333(a)(1) and 352(f).

CARMEN M. ORTIZ
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